

IMPLANTABLE MEDICAL DEVICES

BACKGROUND

The present invention relates to implantable medical devices and methods for making and using such devices, and more particularly, but not exclusively, relates to devices for promoting bone and/or tissue ingrowth, supporting the natural bone remodeling process through osteoclast and osteoblast activity, and/or for stabilizing and promoting bone and/or tissue fusion between adjacent bones or bony tissues.

Various types of devices, implants and systems have been used to stabilize and promote bone and tissue fusion between adjacent bones or bony tissues in a patient. In one form, implants or devices formed of autograft (bone removed from the patient) or allograft (bone taken from another person) have been used because of their osteoinductive and/or osteoconductive properties. However, various difficulties have been encountered with the use of autograft and allograft. For example, autograft presents high incidences of donor site morbidity, the necessity of a painful second 'harvesting' surgical procedure, and the absence of large quantities of bone available for grafting, while allograft presents concerns related to disease transmission, difficulty of procurement and processing, uncertain immune response, and premature resorption. In addition, various considerations related to the anatomical space in which the implant or device is implanted, such as compressive loads for example, can present difficulties in implementing autograft or allograft and/or cause undesirable side effects if autograft or allograft is utilized.

While developments in the stabilization and fusion of adjacent bones or bony tissues have provided steps in the right direction, there remains a need for further development in this area of technology.

SUMMARY

One non-limiting embodiment of the present application is directed to an implantable medical device. In one aspect of this embodiment, the device is configured for promoting bone and/or tissue ingrowth, supporting the natural bone remodeling process through osteoclast and osteoblast activity, or for stabilizing and promoting bone and/or tissue fusion between adjacent bones or bony tissues, although devices configured for providing a combination of some or all of the foregoing features are disclosed.

In another embodiment, an implantable medical device includes a body including an external surface defining an outer profile of the device. The body also includes a porous matrix including a series of interconnected macropores defined by a plurality of interconnected struts each including a hollow interior. A filler material substantially fills at least a portion of the series of interconnected macropores. A plurality of openings extend through at least a portion of the external surface and communicate with the hollow interior of at least a portion of the plurality of interconnected struts. In a further aspect of this embodiment, the external surface is defined by the plurality of openings, exposed areas of the porous matrix, and exposed areas of the filler material. In another aspect of this embodiment, the porous matrix is formed of a ceramic material and the filler material is a polymeric material. In yet a further aspect, the ceramic material is bioresorbable and the polymeric material is biologically stable. In still another aspect, the filler material is infused throughout and substantially fills each one of the series of interconnected macropores.

In still another embodiment, a method includes providing an implantable medical device that includes a body including an external surface defining an outer profile of the device. The body also includes a porous matrix including a series of interconnected macropores defined by a plurality of interconnected struts each including a hollow interior; a filler material substantially filling at least a portion of the series of interconnected macropores; and a plurality of openings extending through at least a portion of the external surface and communicating with the hollow interior of at least a portion of the plurality of interconnected struts. The method further includes positioning the device between adjacent bony portions. In a further aspect of this embodiment, positioning the device between adjacent bony portions includes inserting the device into a disc space between adjacent vertebral bodies.

In yet another embodiment, an implantable medical device includes a body including an external surface defining an outer profile of the device. The body also includes a bioresorbable ceramic matrix including a series of interconnected macropores defined by a plurality of interconnected struts that further define a plurality of interconnected passages isolated from the series of interconnected macropores. A biologically stable polymeric material is infused throughout and substantially fills the series of interconnected macropores, while the plurality of interconnected passages are substantially free of the polymeric material. In one aspect of this embodiment, at least a portion of the plurality of interconnected passages extends through and opens at the external surface of the body. In another aspect of this embodiment, the body is configured to be positioned between adjacent bones or bony tissue, and the external surface includes oppositely positioned bone engaging portions each including a plurality of bone engaging projections structured to engage with the adjacent bones or bony tissue.

In another embodiment, a method for producing a medical implant includes providing a bioresorbable ceramic matrix including a series of interconnected macropores defined by a plurality of interconnected struts, the interconnected struts including a plurality of interconnected internal passages positioned therein; impregnating the ceramic matrix with a biologically stable polymeric material to provide a composite blank; and processing the composite blank to provide an implant body including an external surface defining an outer profile of a desired configuration and shape for implantation, the processing including exposing at least a portion of the interconnected internal passages at the external surface. In a further aspect of this embodiment, the external surface further includes one or more exposed areas of the polymeric material and one or more exposed areas of the ceramic matrix.

In yet another embodiment, an implantable medical device includes a body having an external surface defining an outer profile of the device. The external surface includes one or more exposed areas of a matrix that includes one or more openings and a biologically stable filler material substantially filling at least a portion of the one or more openings. Following implantation, the matrix undergoes a remodeling process in which osteoclast activity progressively removes portions of the matrix and osteoblast activity progressively replaces the removed portions of the matrix with new bone tissue. Initiation of the remodeling process is generally limited to the one or more exposed areas of the matrix. In one aspect of this embodiment, the initiation of the remodeling process is limited to those areas of the matrix that are exposed at or before implantation of the device. In another aspect of this embodiment, the remodeling process progressively replaces the matrix beginning at the external surface and moving progressively inwardly to the interior of the device until all or sub-